January 4, 2012

VIA ELECTRONIC MAIL

Mr. Bill Hall
Director, News Division
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
7700 Wisconsin Avenue, Suite 920
Bethesda, MD 20857

Re: Freedom of Information Act Appeal - FOI Case No. 39419

Dear Mr. Hall:

Pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and the FOIA regulations of the U.S. Department of Health & Human Services ("HHS" or "the Agency"), 45 C.F.R. Part 5, we are writing to appeal the National Institutes of Health's ("NIH") December 1, 2011 response to our November 7, 2011 FOIA request. See November 7, 2011 Letter from Laura Brust, American Chemistry Council ("ACC"), to NIH Freedom of Information Officer (the "Request") (Enclosure A); December 1, 2011 NIH Response Letter from Kim L. Minneman, Freedom of Information Coordinator, National Institute of Environmental Health Sciences ("NIEHS") (the "Response") (Enclosure B). NIH's response was received by ACC on December 5, 2011.

As discussed below, NIH's Response is incomplete and otherwise deficient. First, although the Request was addressed to the NIH Freedom of Information Officer, NIH referred the Request only to NIEHS and did not search the records of any other NIH institute for responsive information. Second, NIH only provided records related to grant R01ES017452, even though the Zhang et al. (2010) publication indicates other NIH sources of funding. Finally, NIH improperly refused to request records from the grantee in violation of Office of Management and Budget (OMB) Circular A-110. The basis for each of these claims and objections is summarized below.

I. ACC's November 7, 2011 Request and NIH's December 1, 2011 Response

ACC filed a FOIA request on November 7, 2011 seeking all records related to the publication "*Occupational Exposure to Formaldehyde, Hematotoxicity, and Leukemia-Specific Chromosome Changes in Cultured Myeloid Progenitor Cells*" authored by Zhang et al. (2010) (the "Study) and published in the Journal of Cancer, Epidemiology, Biomarkers & Prevention.[1] As stated in the Study, "[t]his study was supported in part by the Intramural Research Program of

[1] Zhang, L.; Tang, X.; Rothman, N.; et al. 2010. *Cancer Epidemiol Biomarkers Prev* 19:80-88.

the NIH (National Cancer Institute) and by the National Institute of Environmental Health Sciences grants R01ES017452 (L. Zhang) and P42ES004705 (M.T. Smith)."[2]

In particular, ACC sought the following categories of documents, except for certain records that the National Cancer Institute ("NCI") had provided in response to a previous, more limited, FOIA request:

1. All Records related to the protocol and methodology for conducting the Study. These include all Records concerning:

    a. Exclusion criteria for Study subjects.

    b. The frequency-matching methodology that has been applied in the Study.

    c. Statistical methods applied for evaluation of the data collected, to include assumptions related to the distribution of the aneuploid cells among individuals in the unexposed and exposed Study subjects (i.e., normal or clonal).

    d. Methods used for conducting the Fluorescence *In situ* Hybridization (FISH) analysis, including the cutoff values for monosomy 7 and trisomy 8, and irrespective of whether or not intact metaphases were required for analysis.

2. All Records related to the information and data obtained regarding the Study subjects. These include all Records (whether in English or Chinese) concerning:

    a. Original questionnaires administered to Study subjects by trained interviewers requesting such information as occupational history, environmental exposures, medical history and current medications, and past and current tobacco and alcohol use.

    b. Spreadsheets or other Records that were developed in order to summarize and/or analyze the information collected as part of the questionnaires administered to each Study subject.

    c. Records identifying the specific factory at which each Study subject was employed.

    d. Records identifying the specific Chinese or Western medicines used by each Study subject.

    e. Records containing the laboratory analytical results from the exposure monitoring conducted with UME diffusion samplers worn by each Study subject.

[2] *Id.* at 87.

f. Data and methods used for estimating 8-hr time weighted average levels for control subjects and exposed subjects.

g. Records that provide the Study subjects' individual clinical chemistry results, to include laboratory standardization, laboratory reference values and interlaboratory comparison statistics.

3. All Records related to any analyses, results (including but not limited to photomicrographs), findings and conclusions resulting from use of the protocol and methodology Records requested in (1) above, with respect to the information and data in the Records requested in (2) above, that have been conducted and that are not included in the published summary of the Study. These include all Records concerning:

a. All FISH analyses of aneuploidy measured *in vitro* in progenitor cells of exposed and non-exposed workers, to include incidence of trisomy of chromosome 7 or monosomy of chromosome 8.

b. All FISH analyses of aneuploidy measured by formaldehyde *in vitro* in progenitor cells.

In response to items 1a, 1b, 1c, 1d, 3a, and 3b of the Request, NIH provided only the Application for Federal Assistance for Grant # R01ES017452-01, which Dr. Zhang submitted to NIH in 2008. NIH also stated that "[b]ecause the data you have requested does not meet one or both of the above referenced criteria [of OMB Revised Circular A-110], NIH will not forward your request under item 2f to the grantee for response." In addition, NIH indicated that the Division of Extramural Research and Training ("DERT") had searched its files and found no records responsive to items 2a through 2g of the Request. Finally, NIH asserted that "the grant records for P42ES004705, "Biomarkers of Benzene Exposure and Leukemia Risk," PI: Dr. Martyn T. Smith, were reviewed and found to be non-responsive to your request because the grant looks exclusively at benzene exposures, not formaldehyde exposure."

II. NIH Did Not Perform an Adequate Search for Records

ACC addressed its request to NIH because the Study stated "[t]his study was supported in part by the Intramural Research Program of the NIH (National Cancer Institute) and by the National Institute of Environmental Health Sciences grants R01ES017452 (L. Zhang) and P42ES004705 (M.T. Smith)." According to Ms. Minneman, NIH referred the Request only to NIEHS for response. Accordingly, NIH did not search the records of any other institute, including NCI, for information responsive to any part of the Request.

In *Valencia-Lucena v. U.S. Coast Guard*, 180 F.3d 321, 325-26 (D.C. Cir. 1999), the D.C. Circuit Court of Appeals discussed an agency's obligation to perform an adequate search in response to a FOIA request:

> An agency fulfills its obligations under FOIA if it can demonstrate beyond material doubt that its search was "reasonably calculated to uncover all relevant documents." *Truitt v. Department of State,* 897 F.2d 540, 542 (D.C.Cir.1990) (quoting *Weisberg v. Department of Justice,* 705 F.2d 1344, 1351 (D.C.Cir.1983)). "[T]he agency must show that it made a good faith effort to conduct a search for the requested records, using methods which can be reasonably expected to produce the information requested." *Oglesby v. United States Dep't of the Army,* 920 F.2d 57, 68 (D.C.Cir.1990) ("*Oglesby I*"). The agency "cannot limit its search" to only one or more places if there are additional sources "that are likely to turn up the information requested." *Id.*; *see also Campbell,* 164 F.3d at 28.

In this case, NIH limited its search to NIEHS, even though there was evidence – in the Study, in the records that NIEHS produced in response to the Request, and in the records NCI produced in response to a previous request – that NCI's records "are likely to turn up the information requested." The Study itself indicated that Zhang et al. received funding from NCI's Intramural Research Program. In addition, Dr. Zhang's Application for Federal Assistance lists Drs. Blanche Alter, Qing Lan and Nathanial Rothman of NCI as collaborators ("unpaid consultants") for the Study. The NCI collaborators stated in their September 23, 2008 letter of support (Enclosure C):

> [W]e worked with your group and investigators at the Guangdong Poison Control Center … to design and carry out a cross-sectional molecular epidemiologic study of workers …. We ensured that state-of-the-art methods were used to characterize exposures in the study factories and in the collection, processing, and storage of a wide range of biological samples from the study. Biologic samples were successfully exported from China last year and are now safely stored at NCI biorepositories in Maryland. Exposure badges were analyzed in Guangzhou, and duplicate badges were analyzed at Analytics Corporation in Richmond, VA. Values from duplicate samples correlated at above 0.9 between samples analyzed at both laboratories.
>
> The focus of our research at NCI is to evaluate hematotoxicity including a detailed analysis of lymphocyte subsets, and genotoxicity using conventional chromosomal aberration analysis of cultured lymphocyte samples. Your proposal complements the research we are carrying out at NCI, and we would be pleased to make available to you all necessary coded biologic samples including blind replicate quality control samples from the study to allow you to accomplish all the specific aims of your proposal. In addition, we have detailed information on demographic factors and other potential confounders for each study subject, and on formaldehyde exposure in the study factories, which will be available for the analysis.
>
> Finally, we would be pleased to work with you and your biostatistics colleagues in the analysis and interpretation of data that would be generated from this proposal, as we have done in previous collaborations.

(emphasis added)

This collaboration is also mentioned on page 62 of the records attached to the Response:

> To examine this question, we have teamed up with our long-term collaborators Drs. Rothman and Lan of NCI, together with colleagues in Guangdong and Utrecht, to perform two biomarker (Formaldehyde Biomarker 1 & 2, FAB1 &FAB2) studies of workers occupationally exposed to formaldehyde in China.

It is clear that these NCI investigators participated in the initial study that is the subject of the Request and have data directly responsive to the Request.

Finally, NCI's Division of Epidemiology and Genetics produced relevant records in response to a May 2010 FOIA request, which requested more limited records related to the Study.

"It is well-settled that if an agency has reason to know that certain places may contain responsive documents, it is obligated under FOIA to search barring an undue burden." *Valencia-Lucena*, 180 F.3d at 327. Therefore, since it appears that NCI may have records relevant to the Request, at a minimum, their records should be searched. Without this search, NIH cannot "demonstrate beyond material doubt that its search was 'reasonably calculated to uncover all relevant documents.'" *See id.* at 325.

III. NIH Should Provide All Relevant Records

In the Response, NIH declined to provide grant records for P42ES004705, "Biomarkers of Benzene Exposure and Leukemia Risk," PI: Dr. Martyn T. Smith, because the records were "found to be non-responsive to your request because the grant looks exclusively at benzene exposures, not formaldehyde exposure." This grant, however, was specifically cited as a source of funding in the Study. Therefore, it is likely that records related to Grant P42ES004705 contain information responsive the Request, which seeks *all* records related to the Study. In addition, the Request was not limited to Records associated with two specific grants (R01ES017452 and P42ES004705) as suggested in the Response. The Request was for all Records related to the Study that *may* also be a part of Grants R01ES017452 and P42ES004705 under the Intramural Research Program of the NIH (National Cancer Institute) and the National Institute of Environmental Health Sciences. NIH should ensure that all records that are responsive to the Request are produced.

IV. NIH Should Have Requested Records from the Grantee Pursuant to OMB Circular A-110

The Shelby Amendment, part of the Omnibus Consolidated and Emergency Appropriations Act for FY 1999, required OMB to amend OMB Circular A-110, which applies to Federal grant awards, "to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act." P.L. 105-277. Revised Circular A-110 provides:

> In addition, in response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that was used by the Federal Government in developing an agency action that has the force and effect of law, the Federal awarding agency *shall* request, and the recipient *shall* provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA.

2 C.F.R. § 215.36(d)(1) (emphasis added).

In the Response, NIH contends that the provisions of OMB Circular A-110 apply to data (1) first produced under a new or competing continuing grant awarded after April 17, 2000, and (2) cited publicly and officially by the Federal Government in support of an agency action that has the force and effect of law. NIH further contends that "[b]ecause the data you have requested does not meet one or both of the above referenced criteria, NIH will not forward your request under item 2f to the grantee for response." Since the grants at issue were awarded well after April 17, 2000, it appears that NIH is asserting that the Study has not been "cited publicly and officially by the Federal Government in support of an agency action that has the force and effect of law."[3]

ACC is aware of the Federal Government citing the Study publicly and officially in support of at least two agency actions:

- HHS cited the Study in support of its substance profile for formaldehyde in the 12th Report on Carcinogens ("RoC"), which was released in June 2011;[4] and
- the U.S. Environmental Protection Agency ("EPA") cited the Study in support of its draft IRIS Toxicological Review of formaldehyde, which was issued in June 2010.[5]

Although "the listing of substances in the RoC only indicates a potential hazard and does not establish the exposure conditions that would pose cancer risks to individuals in their daily lives,"[6] the Report is mandated by Congress. *See* 42 U.S.C. § 241(b)(4). EPA's IRIS Toxicological Reviews are used by federal, state, and international regulatory bodies as a source of health risk information. Once finalized, the toxicity values contained in the Toxicological

[3] Revised Circular A-110 states "[u]sed by the Federal Government in developing an agency action that has the force and effect of law is defined as when an agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law." 2 C.F.R. § 215.36(d)(iii). "Force and effect of law" is not further defined.

[4] U.S. Department of Health and Human Services, *Report on Carcinogens, Twelfth Edition* (2011) ("12th RoC"), available at http://ntp.niehs.nih.gov/ntp/roc/twelfth/roc12.pdf.

[5] U.S. Environmental Protection Agency, *Toxicological Review of Formaldehyde - Inhalation Assessment (CAS No. 50-00-0) In Support of Summary Information on the Integrated Risk Information System (IRIS)* (External Review Draft) (June 2, 2010), available at http://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=223614.

[6] 12th RoC, at 3.

Review of formaldehyde will be used as the basis of a number of regulatory actions. For example, in promulgating National Emission Standards pursuant to Section 112 of the Clean Air Act, EPA relies upon IRIS values for various substances, including formaldehyde, when determining emission levels. Moreover, the International Agency for Research on Cancer ("IARC") cited the *in press* manuscript in its 2009 summary from the October 2009 meeting[7] and in the subsequent Monograph for Formaldehyde. Therefore, the Request should have been forwarded to the grantee for response.

* * *

For all the reasons discussed above, we respectfully request that NIH:

(1) search the records of NCI and any other NIH institute that may have records responsive to the Request;

(2) provide all responsive records, including records related to Grant P42ES004705; and

(3) request responsive records from the grantee in accordance with OMB Circular A-110.

Thank you for your prompt consideration of this appeal. If it would be helpful to discuss any aspect of this appeal, please contact me at (202) 249-6139, or Laura_Brust@americanchemistry.com.

Sincerely,

Laura A. Brust

Laura A. Brust
Assistant General Counsel

Enclosures

[7] Special Report: Policy. A review of human carcinogens – Part F: Chemical agents and related occupations. *The Lancet*. 10:1143-44.